JUN - 7 2000

K001548

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
Modular Rotating Hinge Knee Crossover Tibial Bearing Components

Proprietary Name: Modular Rotating Hinge Knee Crossover Tibial Bearing Components

Common Name: Crossover Tibial Bearing Component

Classification Name and Reference: Knee joint femorotibial metal/polymer constrained cemented prosthesis
21 CFR §888.3510

Proposed Regulatory Class: Class II

Device Product Code: OR (87) KRO

For Information contact:
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This Special 510(k) submission is intended to address a design and material modification to the Kinematic™ Rotating Hinge Knee tibial bearing component and the Modular Rotating Hinge Knee Tibial Rotating Component. The predicate devices are cast Vitallium® (CoCr) Alloy bearings and polished stems conforming to ASTM F75 that fit inside an UHMWPE tibial insert or all-poly tibial component. These predicate devices were found substantially equivalent via the 510(k) process. The subject device is being modified to mate with the tibial component of the Kinematic™ Rotating Hinge Knee System and the femoral component of the Modular Rotating Hinge Knee System and will be fabricated from forged Vitallium® Alloy conforming to ASTM standard F799.

The Modular Rotating Hinge Knee Crossover Tibial Bearing component is intended for replacement of the bearing surfaces of the distal femur and proximal tibia to relieve pain, instability, and restriction of motion due to degenerative bone disease or failed previous prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2000

Ms. Elizabeth A. Staub
Vice President
Regulatory Affairs, Quality Assurance and Clinical Research
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K001548
Trade Name: Modular Rotating Hinge Knee Crossover Tibial Bearing Components
Regulatory Class: II
Product Code: KRO
Dated: May 17, 2000
Received: May 18, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K001548

Device Name: Modular Rotating Hinge Knee Crossover Tibial Bearing Component

Indications for Use:

These devices are intended to be implanted with bone cement in cases of destruction of the joint surfaces, with or without significant bone deformity where the cruciate and/or collateral ligaments are absent or do not stabilize the knee joint; knees where the ligaments are inadequate and/or the musculature is weak; and revision of a failed prostheses where there has been gross instability, with or without bone loss or inadequate soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Lochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001548